Fostering Research Integrity through Educational Programs: Lessons Learned at the University of Minnesota

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The implementation of a Public Health Service (PHS) policy on Instruction in the Responsible Conduct of Research (RCR) would be a significant challenge to universities because of its broad inclusion of personnel involved in research. The University of Minnesota is already meeting this challenge with the delivery of a comprehensive educational program to over 2,000 faculty and principal investigators (PIs) in calendar year 2000.

The University of Minnesota is a large, land-grant institution. The intellectual diversity of the institution is reflected in its 21 collegiate units, 3,000 tenure and tenure-track faculty, and 10,000 graduate students enrolled in 150 masters and doctoral programs. The foundation of our educational programming in RCR developed centrally, early in the 1990's, to support the educational requirement of training grants. These programs were expanded to faculty in the mid-90's in response to growing institutional and national concern about misconduct in research. The current curriculum is the result of an institutional corrective action plan initiated by National Institutes of Health (NIH) in 1997. Therefore, a unique set of circumstances required the University of Minnesota to implement a comprehensive educational program in RCR before announcement of the PHS policy on Instruction in RCR.

Our goal is to share the experience of our institution in order to aid others in the development of programs to meet the requirements of the PHS policy. Points of discussion within the context of the evolution of the educational program at Minnesota include 1) policy as framework for education, 2) development and delivery of the curriculum, 3) resources and financial investment, and 4) evaluation.

Policy as Framework in Education

One strength of the educational initiative at the University of Minnesota is that the importance of RCR is reflected in institutional policies. The Board of Regents, the administrative authority of the

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University, passed the Code of Conduct in 1996. This policy pertains to all members of the University community and states that we will "adhere to the highest ethical standards of professional conduct and integrity." While affirming the common values of research and scholarship, it is a clear demonstration of institutional ownership of these values. In 1999, the Board of Regents passed a revised policy on Principal Investigator Eligibility on Sponsored Projects. This policy requires PIs to complete a required education in RCR before any awarded funds are released for spending. The policy was implemented March 1, 2001, preceding the PHS policy by approximately two years and providing the motivation for compliance with the educational requirement. Both policies can be viewed at http://www.ospa.umn.edu/policy/respolcy.htm.

The University of Minnesota has a strong tradition in faculty governance, so it is not surprising that the faculty senate has also promoted RCR. In 1999, the faculty senate passed the policy on Education in Responsible Conduct of Sponsored Research and Grants Management (see http://www1.umn.edu/usenate/policies/grantsmgmt.html). Whereas this policy reiterates the expectation that PIs and project personnel have the responsibility to behave in accordance with the highest ethical standards, it also defines the responsibility of the University to provide individuals involved in research with information and resources that support responsible conduct. The policy describes the framework for implementing educational programs under the leadership of the Vice President for Research and Dean of the Graduate School. It outlines the formation of three advisory committees, one for each major constituency: Academic personnel (including faculty and academic administrators), research staff (including graduate and postdoctoral trainees as well as project staff), and administrative staff (including accounting and secretarial support). The charge to each of these committees is to define the educational needs of the constituency, develop the curriculum, recommend delivery formats for the curriculum, propose appropriate recognition/accreditation, and establish appropriate continuing education requirements. The Vice President for Research and Dean of the Graduate School is also charged with the responsibility of maintaining a database

on meeting the educational requirements.

Development and Delivery of the Curriculum

The development and delivery of the educational program in RCR for investigators has been led by the Faculty Education Advisory (FEA) Committee. The FEA Committee is in its third year of existence and is made up of faculty, with senior administrators serving in ex officio capacity. The Committee is staffed by personnel from the Office of the Vice President for Research. The Committee meets monthly and has had remarkably consistent participation over the three years. Members were added recently to increase representation of disciplines within the University.

Members of the FEA Committee are senior and respected faculty and broadly represent the diversity of the University's colleges, departments, and programs. The commitment of faculty leaders, coupled with resources and commitment from high-level University administration, has been crucial to the success of the FEA Committee's effort. The Committee has focused on three areas in RCR education: (1) defining and identifying the target populations; (2) identifying topic areas; and (3) implementation.

Defining and identifying target populations for RCR education and training
The initial focus of RCR educational programming has been PIs, both because it represents the largest group of faculty and staff responsible for the performance of research, and because the University has a system for certification of PI status. This cohort represented nearly 2,000 individuals, from across every college and a diverse range of departments and research areas.

This diversity led to a recognition that education in RCR could not be successful as a "one size fits all" program, and that we needed to speak to the needs and interests of researchers from outside biomedical research areas. But in spite of the diversity of researchers' needs, the FEA Committee agreed on a need to achieve a shared basic level of understanding for all researchers on a core set of RCR issues. This is based on the view that all researchers belong to the University's research community, and that

such membership brings with it certain responsibilities, including basic familiarity with the rule and issues in areas such as research that involves human or animal subjects. So while many researchers may never engage in human or animal research, it is unacceptable for them to pass it off as someone else's problem. For those researchers engaged in research involving human or animal subjects, more in-depth education and training in those areas is required. In addition to both basic training for all and in-depth training when appropriate, the FEA Committee is developing recommendations for continuing education in RCR.

Identifying topic areas

The FEA Committee's second task was to identify topic areas for curriculum development. Since our efforts pre-dated the PHS/Office of Research Intetrity (ORI) draft of final guidelines, an initial list of topics was drawn from the list of suggested topic areas in the ethics requirement for NIH Training Grants (T32). The FEA Committee then worked to make the list of topics relevant to PIs._The current list of topics includes:

  Social Responsibility and Misconduct
  Authorship and Peer Review
  Data Management
  Intellectual property
  Conflict of Interest
  Fiscal Responsibility
  Human Subjects
  Animal Subjects
  Environmental health and Safety

After the PHS/ORI guidelines were issued, we compared our list of topics to the guidelines in an effort to assess what changes, if any, are needed, and determined that we need to add content on both collaborative science and mentoring.

Implementation

After identifying the target population, and the topic areas that would be covered, the FEA Committee's last task was to develop strategies for implementation. Key components in our effort include recruiting instructors with appropriate expertise and experience, drawing mostly from the ranks of the faculty; and a commitment that face-to-face interaction be part of the educational experience.

We have employed three separate formats for instruction—classroom sessions totaling six hours; web-based instruction for some financial and grants management topics, followed by a 1.5 hour classroom session; and in-depth special topic instruction involving a 1.5 hour classroom session, web resources, and case studies.

Because of the number of hours of instruction required and the diversity of investigators who need to participate, a large and diverse pool of instructors was recruited. We have between four and six faculty who are prepared to deliver one topic area; faculty are paired with relevant professional staff for some topics. These 37 instructors represent 13 colleges and 3 administrative units, and include 4 department heads, and 2 associate deans. While all of the faculty agreed to teach in our RCR efforts on a volunteer basis, the FEA recommended and the University's Vice President for Research agreed that formal and material acknowledgement of their efforts is appropriate. To that end, funds were committed to provide small professional development awards to all faculty participating as instructors in the RCR programs.

Resources & Financial Investment

A cornerstone of our program is faculty involvement in the delivery of the curriculum. Faculty are presenters or facilitators of discussion for each topic. For some topics they are partnered with staff who are available to answer more technical questions. For example, faculty who deliver the module on Intellectual Property are paired with a staff member from the University office of Patents and Technology Marketing. Faculty are also involved in revising instructional materials used in workshops and on the web, as well as the curriculum itself.

The commitment of respected, senior faculty, demonstrated by their leadership on committees or their development of the curriculum, enabled us to recruit other faculty for the delivery of the curriculum. Another critical element for recruitment was a detailed syllabus for each topic of the curriculum. The syllabus includes learning objectives, relevant policies, principles, issues for discussion, reference materials, and case studies for some topics.

One limitation of the curriculum was its bio-medical flavor, particularly in case studies, largely because of the disciplines represented on the initial faculty advisory committee. Recognizing this, we targeted faculty in

underrepresented disciplines to achieve greater balance for delivery of the curriculum. Over 50 faculty from 34 departments are currently involved in RCR curriculum development or delivery. Besides enriching the curriculum, we believed that faculty involvement throughout the University would increase ownership and spread commitment to the RCR. An unexpected outcome of the diversity of disciplines has been the high level of interest maintained by the faculty as they see the issues in their topic take on new dimensions and challenges from one discipline to another.

Besides the demonstrated commitment of faculty, a successful educational program in RCR requires strong support services. Instructional materials are revised and shared amongst presenters. When the faculty audience asks previously unanswered questions, the experts are consulted. The answers are incorporated into future workshops, and the curriculum and instructional materials are revised as appropriate.

There are also numerous administrative tasks associated with scheduling presenters, rooms, and equipment; preparation of printed and web based materials; registration and documentation of attendance; tabulation of evaluations; and feedback to and coaching of faculty presenters. Although these activities happen mostly behind the scenes, they are critical to the program.

Finally, communication is a critical support service. Requirements and rationale must be conveyed to the faculty and other research personnel; progress must be reported to the advisory committee (FEA), faculty senate committees, administrative offices, and academic administrators. All available communications vehicles are used, including monthly newsletters of the sponsored projects office and of colleges as well as the University's multiple publications; printed brochures and flyers; web based home pages and events calendars; meeting in person with faculty committees, academic deans, and special constituencies (IRB); and e-mailings from the Vice President of Research, Deans, and Department heads or chairs.

So what does all of this cost? The direct expenses of the 62 workshops for 2,400 investigators over a 12-month period is the most straight forward. Based on actual cost to date for printing of materials, rental of rooms and equipment, and similar expenses, these direct expenses are projected to be $48,600, or $15.20 per person per session. This amount does not include any compensation for the faculty involved in the delivery. Based on the average actual salaries of faculty involved in the workshops, with an average of 1 – 2 hours depending upon the topic, the value for delivery would be an additional $32,300. This does not include any estimate of faculty time for preparation or involvement in discussions, via e-mail or in person, of improvements or additions to the materials, sharing of additional references, or similar and recurring work. Although faculty were recruited without any hint of monetary reward, we were able to give those most involved small professional development grants of $1,000 – 2,000, for an expense of $24,000.

Direct administrative costs include the salary and fringe benefits of 1.75 staff years: one full time program coordinator, a 50% administrative appointment of a faculty member acting as program director; and an administrative fellow (graduate student). However, the direct cost of additional support services including design and maintenance of web-based tutorials as well as registration and recording keeping activities are nearly impossible to tally since they are provided by a number of centralized offices from the graduate school administration to the human resources offices.

Hardest yet to calculate are the cost of faculty hours spent in participation. Since the University of Minnesota has no formula for faculty productivity or opportunity costs, one simple estimate was based on salary. Applying the composite faculty salaries for Category 1 universities in our region from the March 4, 2000, issue of *Academe* and the University of Minnesota fringe benefits rate against the estimate of 9,600 hours spent by faculty in workshops or reading materials, we estimate the cost of faculty participation at $425,000. However, the benefit side of this equation is even harder to estimate. Certainly the potential liabilities exceed the total cost of the program, including loss of faculty time.

Evaluation

Assessing for continuous course improvement The RCR curriculum is currently offered in 2 parts of 3 hours each. At the end of each session, participants are asked to complete a one-page course evaluation form which asks 1) whether the level of content for each topic is appropriate, 2) whether the information on each topic is

useful, 3) whether the session increased your understanding, and 4) whether the materials and resources were helpful. Finally, there is a place for comments. Data from these forms have been summarized and used to make course improvements.

During the first 6 month period, 66% of the participants (N=522) returned the evaluation for part 1; 43% (N=1162) for part 2. In general, 80% of the participants judged the material presented to be appropriate. Lists of resources and websites were considered the most useful resources. Early on, criticisms outpaced satisfactory remarks 3 to 1. Constructive comments included: make the course more interactive, provide readings ahead of time, incorporate web based materials, and shorten the length of time. Subsequent iterations of the course adopted these suggestions. As a result, the overall rating of usefulness improved, from 2.7 to 3.0 on a 4 point scale (with 4 being very useful) for part 1 and from 2.5 to 2.9 for part 2. In addition, there were fewer critical comments, and the number of statements of praise increased.

Reflecting on the course evaluation data and our efforts at course improvements, we have identified the following contributors to participant satisfaction:

Interactive programming. The more interactive the program, the more it is viewed as useful.

Group size. Smaller groups are better received than larger groups.

Presenters from diverse disciplines. Participants have been less satisfied when the presenters are all from the same discipline.

Topic. Some topics seem to be inherently more interesting than others. For example, authorship seems to be rated as most interesting irrespective of who presents the material. Other topics, like intellectual property and conflict of interest typically get lower ratings for usefulness. However, when we have broadened the topic of intellectual property to include more on copyright, there were some improvements in rating. Staff have speculated that in areas like intellectual property and conflict of interest may be inherently dissatisfying as it is seldom possible for the presenter to give definitive answers to questions.

Assessing promotion of responsible conduct

Documenting faculty participation in an initial and on-going educational program in RCR demonstrates compliance with a federally mandated corrective action plan (e.g., the NIH plan currently in effect for the University of Minnesota). It does not, however, provide evidence that the attitudes, values, and behaviors that gave rise to the disciplinary action have changed. Likewise, installing a model system for financial accountability, such as the Electronic Grants Management System (EGMS), can alert an individual faculty member and his/her unit head when a proposed action is not within the bounds of sanctioned behavior. It does not, however, assure that the moral climate in which research is conducted is enhanced, or will it necessarily improve the ability of investigators to interpret ambiguous situations and identify better choices. If we hope to provide evidence that we have improved the integrity of the researcher and climate of the institution, we need measures that assess the more elusive outcomes of the research ethics enterprise and that can be used to examine the effectiveness of our educational programs and compliance systems.

In Fall of 1999, a faculty group was convened to identify opportunities for assessment of outcomes. The following were identified:

Self-assessment questions in web-based modules. Self assessment items have been included in several topics: Fiscal Responsibility, Intellectual Property, Conflict of Interest, Informed Consent, Protecting Human Subjects. Although self assessment items are included, we have decided not to invest resources to assess knowledge level outcomes.

University-wide climate surveys to track perceptions of ethical research practices. The last Faculty and Staff Climate Survey of the University of Minnesota was conducted in 1997, with a summary reported in 1999. Questions are being prepared for the next survey. The purpose will be to track perceptions of the extent to which the University climate supports ethical conduct generally. Questions would be directed toward ethical research practices as well as issues of academic integrity.

Narrative interviews of unit administrators. In addition to eliciting their perceptions of the norms of research conduct, interviews with unit administrators is a way of identifying areas needing attention.

Graduate student perceptions of the doctoral experience. Melissa Anderson directs the

Academic Life Project, funded by NSF, which studies the normative experiences of doctoral students (see paper by M. Anderson in these proceedings for additional information on this study).

Adaptation of measures of ethical reasoning and role concept.   One reason for the paucity of information on assessment of instructional effects in this area is the lack of well-validated outcome measures. Measures must be grounded in a well-established theory of ethical development and be sufficiently user friendly to enable their use for a variety of purposes. We propose to develop two outcome measures: (1) a measure of ethical reasoning and judgment about common problems arising in the research setting, and (2) a measure of role concept, i.e., how the researcher understands his/her role relative to other researchers. The measures will assess two of the four dimensions of competence described by Rest's Four Component Model of Morality (Rest, 1983). The areas are chosen because prior studies support the usefulness of the methods for outcome assessment and for demonstrating the links between performance and day-to-day ethical behavior. The two measures will be modeled after existing measures designed for assessing the outcomes of ethics education in dentistry. (See paper by M. Bebeau in these proceedings for additional information on these approaches).

In summary, a national effort is required to design outcome measures that can be used to assess the effectiveness of institutional education programs in RCR. Measures must well-grounded theoretically, well validated, and sufficiently user friendly to enable their use for a variety of purposes. Such purposes may include: 1) determining the range of criteria that define competence in topic areas among different disciplines, 2) conducting a needs assessment to identify areas where instructional resources should placed, 3) identifying individual differences or problems that require intervention or remediation, 4) providing feedback to individuals, departments, and institutions on research ethics competence, 5) determining the impact of current programs, and 7) studying the relationship between competence and ethical behavior.

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